

§ 35.300

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§35.100 and 35.200.

[67 FR 20370, Apr. 24, 2002, as amended at 70 FR 16364, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 45151, Aug. 13, 2007; 74 FR 33905, July 14, 2009]

Subpart E—Unsealed Byproduct Material—Written Directive Required

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under §32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under §30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§35.290, 35.390, or

(3) An individual under the supervision, as specified in §35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physi-

10 CFR Ch. I (1–13 Edition)

cian who is an authorized user in paragraph (b)(2) of this section; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 71 FR 15009, Mar. 27, 2006; 72 FR 55932, Oct. 1, 2007]

§ 35.310 Safety instruction.

In addition to the requirements of §19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under §35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include—

(1) Patient or human research subject control;

(2) Visitor control, including—

(i) Routine visitation to hospitalized individuals in accordance with §20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with §20.1301(c) of this chapter;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with §35.2310.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003]

§ 35.315 Safety precautions.

(a) For each patient or human research subject who cannot be released under §35.75, a licensee shall—

(1) Quarter the patient or the human research subject either in—

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who